



BRS Stakeholder Update



Summer 2007

Message from the Deputy Administrator

Hello! APHIS' Biotechnology Regulatory Services (BRS) program accomplished a significant achievement this summer with the publication of its draft programmatic environmental impact statement (EIS). We are extremely proud of all of the hard work that was put into this document and I'm especially pleased as the newly named BRS Deputy Administrator to congratulate all of the BRS employees for their efforts on the draft EIS.

We hope you find this stakeholder update informative, and encourage you to visit our Web site (<http://www.aphis.usda.gov/biotechnology>) for the latest news and information. If you have not previously registered with our on-line BRS stakeholder registry, please go to <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf> and sign up to ensure that you receive all future stakeholder updates.

Sincerely,

Rebecca Bech
BRS Deputy Administrator

BRS Announces Draft Programmatic Environmental Impact Statement

On July 12, 2007, BRS announced the availability of its draft environmental impact statement (EIS) that evaluates potential revisions to existing regulations regarding the importation, interstate movement, and environmental release of genetically engineered (GE) organisms. The draft EIS outlines several key areas BRS is evaluating and seeking public comments on, including expanding BRS' regulatory scope through additional provisions in the Plant Protection Act (PPA) of 2000, utilizing a tiered permitting system based on potential environmental risk, and implementing a process for continued oversight of crops that do not meet the criteria for deregulation.

Input received regarding these areas and all aspects of the draft EIS will enable BRS to make an informed decision regarding any possible future changes to the regulations. Ultimately, BRS will formulate a proposed rule based on information in the draft EIS, the latest scientific information, and public comments.

Because the public is a key partner in the EIS process, APHIS is scheduling four public meetings in August in the Washington, D.C. area, Missouri, and California, to allow interested parties to talk with BRS officials about the issues addressed in the draft EIS in person. The forums will be held:

- August 1, 2007, from 4 p.m. to 7 p.m. in Riverdale, MD;
- August 3, 2007, from 4 p.m. to 6 p.m. in Riverdale, MD;
- August 16, 2007, from 4 p.m. to 7 p.m. in Davis, CA; and
- August 30, 2007, from 4 p.m. to 7 p.m. in Kansas City, MO.

The draft EIS, a fact sheet, and details about the public meetings are posted at <http://www.aphis.usda.gov/newsroom/>.

BRS Signs Memorandum of Understanding with U.S. Fish and Wildlife Service

In May, BRS signed a Memorandum of Understanding (MOU) with the U.S. Fish and Wildlife Service (FWS) to define and clarify policies and procedures for interaction between BRS and FWS in order to comply with the consultation requirements of the Endangered Species Act (ESA). The MOU identifies when BRS actions and decisions, taken during the process of regulating the release of GE plants, require an effects analysis in accordance with the ESA. The primary principle underlying this agreement is cooperative partnership. The ESA requires the involvement of all Federal agencies in the protection and recovery of our Nation's biological diversity. The FWS and BRS are entering into this agreement to affirm a partnership to enhance the realization of the goals of ESA, and specifically section 7 of the ESA. This partnership will also seek to efficiently and effectively fulfill the requirements of section 7 of the ESA.

NEPA Changes

BRS recently modified its National Environmental Protection Act (NEPA) implementing procedures. To ensure that BRS is developing consistent and comprehensive assessments under NEPA, BRS is checking critical habitat information, GPS coordinates, and filling out NEPA forms for each application received. Aside from the new NEPA procedures, other changes are taking place within the e-Permitting system. Although many of these changes will not directly affect applicants, some changes may. BRS is requesting that all applicants submit their applications as soon as possible to ensure timely review. For those applicants submitting permits that may require an environmental assessment, please contact BRS as soon as possible to discuss timelines in more detail. This request for additional processing time will allow BRS to thoroughly complete the appropriate analyses and meet the required deadlines.

GE Alfalfa Update

Following a May 3, 2007, permanent injunction by the United States District Court requiring BRS to issue an Administrative Order specifying conditions for Roundup Ready alfalfa growers and to publish the locations of alfalfa production acreage as soon as practicable, APHIS filed a motion to amend and clarify the judge's decision. In response to this motion, on June 26, the judge ruled on the above issues and reached the following conclusions:

1. Roundup Ready alfalfa may need not be stored in containers and need be labeled only if it leaves the farm of origin.
2. APHIS will provide growers with a best practices document regarding the cleaning of harvesting equipment, rather than approve practices proposed by growers.
3. Monsanto and Forage Genetics have 60 additional days to collect and provide to APHIS field size and GPS coordinates of Roundup Ready alfalfa fields in the United States.
4. APHIS will post on its website only the counties where Roundup Ready alfalfa is grown and will only provide additional information in response to specific requests from farmers. The additional information will be the distance from the farmer's fields to the nearest Roundup Ready alfalfa fields.

On July 12, 2007, APHIS issued an Administrative Order specifying mandatory production practices that must be implemented by Roundup Ready alfalfa producers. The requirements specified in the Administrative Order apply to all Roundup Ready alfalfa planted between June 14,

2005 and March 30, 2007 and will remain in effect for as long as Roundup Ready alfalfa is a regulated article under 7 CFR Part 340. In addition, APHIS posted on its Web site a list of states and counties where Roundup Ready alfalfa is grown, and will update the list as new information is provided to APHIS by industry.

The court decisions and BRS actions were in response to a lawsuit filed by the Center for Food Safety --along with several other nonprofit organizations and alfalfa growers—challenging APHIS' decision to deregulate the Roundup Ready alfalfa lines. The court ruled that the deregulation may have significant environmental impacts that require the preparation of an EIS, and that APHIS violated NEPA by preparing an environmental assessment (EA) instead of an EIS. On February 13, 2007, the United States District Court ruled that APHIS must prepare an EIS in support of its 2005 decision to deregulate Roundup Ready alfalfa. For more information on this issue, please visit <http://www.aphis.usda.gov/biotechnology/alfalfa.shtml>.

BRS Employee Spotlight

In each quarterly stakeholder update, BRS will highlight one of our employees so that our stakeholders can see the variety of work done in our program.

Employee: Mike Wach

Position: Chief, Regulatory Analysis Branch

Years with BRS: Almost 4 – I joined BRS in November 2003.

Activities prior to joining BRS: I worked for ten years in agricultural biotechnology research and development, finding ways to genetically engineer corn, wheat, and tomatoes. Then I attended law school, specializing in environmental law, and I practiced for several years in Eugene, Oregon, with a non-profit environmental law firm.

Education: I have a B.S. in agronomy from Cornell University, a M.S. in plant physiology from the University of California, Davis, and a Ph.D. from Cornell University in plant pathology. My dissertation research was on *Streptomyces acidiscabies*, one of the bacterial pathogens that causes potato scab. I received my J.D. from the University of Oregon.

Job Description: In addition to the production of BRS' recently announced programmatic EIS, my focus is on regulatory interpretation and policy development. I also provide guidance to the biotechnology staff on compliance with various environmental laws, especially the National Environmental Policy Act.

Proudest Accomplishment: As we undertook the process of revising our regulations, I wanted to make sure everyone at BRS had the opportunity to participate in the process and contribute their thoughts and suggestions. With the help of our Policy and Program Development staff, I organized a 2-day workshop for all BRS staff to work together to propose changes to the regulations. The teams assembled for the workshop considered and analyzed hundreds of suggestions for improvements to the rules, and I received many positive comments from the participants.

What motivates you about your job: It never gets boring. Not a day goes by that I'm not asked to work on some novel question.

Administrative Update

We are pleased to announce that Sidney W. Abel, III, became BRS Assistant Deputy Administrator in June. Sidney worked for the U.S. Environmental Protection Agency (EPA) since 1989, where he most recently served in the position of Associate Director. He was responsible for planning and developing program strategies and provided oversight of risk assessments and drinking water exposure characterizations for pesticide and inert chemicals in support of national registration programs; provided oversight of science policy, communication, and coordination with EPA and external partners; and served as the Division's international liaison on pesticide activities with other emerging markets. Sid received his Bachelor's degree in Soil and Water Pollution from the University of Maryland and his Master's degree in Environmental Science from George Washington University.

Janet Carpenter recently joined the BRS staff as an Agriculturalist on the International Policy Team in the Policy Coordination Division of BRS. Janet comes to BRS from the U.S. Agency for International Development (USAID), where she served as a Biotechnology Advisor since 2002. Prior to joining USAID, Janet worked at the National Center for Food and Agricultural Policy, where she conducted research on the benefits and risks of agricultural biotechnology, among other topics. Janet has a Bachelor's degree in Economics from the University of Wisconsin and a Master's Degree in Agricultural and Resource Economics from the University of Maryland.

We are sad to announce that in September, BRS State Liaison Catherine Preston is leaving BRS to join APHIS' Plant Protection and Quarantine program in Gainesville, Florida. Through Catherine's hard work, BRS has greatly enhanced its relationship with our state partners. We wish Catherine the best of luck in her new endeavors.

Interested in Working in BRS?

If you or someone you know is interested in working for BRS, you can view and apply for current job vacancies by visiting <http://jobsearch.usajobs.opm.gov/> and searching for "Biotechnology Regulatory Services" (in quotes).

Have questions about BRS policy and regulations? E-mail us at biotechquery@aphis.usda.gov

Year-to-Date Submissions through June 30, 2007

Notifications Acknowledged

134	Importation
178	Interstate Movement
188	Environmental Release
424	Combined Interstate Movement/Release

Permits Issued

10	Importation
26	Interstate Movement
17	Environmental Release
7	Combined Interstate Movement/Release
340	Courtesy Permits

3 Petitions/Extensions to Grant Non-Regulated Status Received